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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/649,582 | 08/27/2003 | James Brugger | 53951-093 | 8937 |
| 21890 | 7590 | 03/22/2006 | EXAMINER | |
| PROSKAUER ROSE LLP PATENT DEPARTMENT 1585 BROADWAY NEW YORK, NY 10036-8299 | | | DEAK, LESLIE R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3761 | |

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/649,582 | BRUGGER ET AL. | |
| | Examiner | Art Unit | |
| | Leslie R. Deak | 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8/27/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 6, 7 rejected under 35 U.S.C. 102(b) as being anticipated by US 5,476,592 to Simard.

In the specification and the figures, Simard discloses the apparatus as claimed by applicant. In particular, Simard discloses a hemofiltration apparatus with a fluid circuit with a blood path 5, 6, filtrate line 10 connected 3 across a porous membrane 4 to the blood portion 2, and a replacement fluid line 22. The replacement fluid is passed through in-line sterile filter 15, 24 for removing pyrogens (see FIG 1, column 2, lines 45-67, column 3, lines 1-20). The circuit comprises a drip chamber 8 with two inlets or connectors that allow the filtered blood (which may comprise a replacement fluid, since it is replacing the fluid drawn into the circuit) and the substitute or replacement fluid to be connected to the return line 6. The device further comprises pump 7 in the blood draw line 5, pump 14 in filtrate line 10, and pump 23 in replacement fluid line 22.

Applicant presents claims drawn to a "kit" of the claimed components. However, applicant has not set forth in the specification what, exactly, comprises the kit, other than the claimed components. Therefore, examiner has interpreted the claims to mean that the claimed components comprise the claimed kit.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3-5, 8, and 9-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,476,592 to Simard, as applied above, in view of US 5,441,636 to Chevallet et al.

In the specification and figures, Simard discloses the apparatus as claimed with the exception of a cassette, support or tray that supports the fluid circuit, filter, and other components.

Chevallet discloses a fluid handling cassette 20 that may comprise a blood supply and return line, a dialyzer, diasylate circuit, and a replacement fluid circuit. The placement of all the components in a support or cassette allows for reduced pre and post-procedure handling and connection, reducing connection errors, and lends itself to sterile packaging and safe disposal. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the fluid lines, filters, and pumps disclosed by Simard in a support cassette as disclosed by Chevallet, in order to reduce preparation time and errors, as taught by Chevallet.

With regard to applicant's claims 4, 5, 11, 13, 14, 15, 20, and 22, drawn to a plurality of connectors and bag spikes, Chevallet specifically discloses that the replacement fluid circuit 80 comprises bag spike 81. It would have been obvious to one

having ordinary skill in the art at the time the invention was made to add plural connectors and spikes, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. See MPEP § 2144.04.

With regard to claim 10, Simard discloses a venous line connected to a patient access (see column 2, lines 50-55) and illustrates filter 15 as disposed between fluid source 11 and blood circuit 5/6, with the replacement fluid line 22 connected via drip chamber 8 to venous return line 6 (see FIG 1).

With regard to claim 17, Chevallet illustrates that support or tray 20 comprises connectors 34 that align the pumping tube portions such that they may engage with roller pumps or actuators 112, 113, 114, 115 on a treatment module.

With regard to claim 19, Simard discloses that the filter has a porosity of 0.22 μ m (see column 3, lines 56-62).

Conclusion

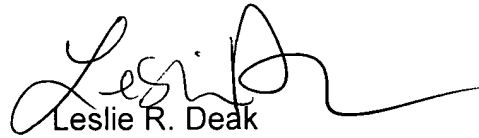
5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. US 5,846,419 Nederlof
 - i. Hemofiltration apparatus with pyrogen filter

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie R. Deak
Patent Examiner
Art Unit 3761
15 March 2006